



UNITED STATES AIR FORCE ARMSTRONG LABORATORY

Test and Evaluation of the Physio- Control Corporation LifePak 10-59 Defibrillator/Monitor/Pacemaker and Military Auxiliary Power Supply (MAPS)

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October 1996

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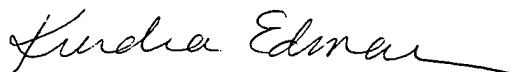
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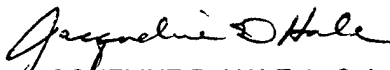
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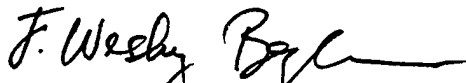
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13. ABSTRACT (Maximum 200 words) The LifePak 10-59 is a portable cardiac monitor, defibrillator and pacemaker. Features include; synchronized defibrillation, electrocardiogram monitoring and noninvasive pacing. A Military Auxiliary Power Supply (MAPS), model 806311-07, allows the LifePak 10-59 to operate from 120 VAC/60 Hz or 120 VAC/400 Hz power sources. Additionally the LifePak 10-59 can receive power via any one of three rechargeable nickel-cadmium(Ni-Cad) batteries located on top of the monitor. The unit offers eight defibrillator energy settings ranging from 5 - 360 joules and is delivered through standard paddles, clip-on posterior or pediatric paddles, or FAST-PATCH disposable electrodes.				
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TEST AND EVALUATION OF THE PHYSIO-CONTROL CORPORATION LIFEPAK 10-59 DEFIBRILLATOR/MONITOR/PACEMAKER AND MILITARY AUXILIARY POWER SUPPLY (MAPS)

BACKGROUND

In January 1991, Aeromedical Research evaluated and approved Physio-Control Corporation's Lifepak 10-43 Monitor/Defibrillator, Part Number (PN) 804200-43, with electromagnetic interference (EMI) modifications for inflight use on USAF aeromedical evacuation aircraft. To avoid confusion with the "non-modified" version, the number "43" appears at the end of the part number on approved Lifepak 10 models. In May 1994, Physio-Control submitted a newer model, the Lifepak 10 Monitor/Defibrillator/Pacemaker, PN 804200-47 identified as the -47 for evaluation and was later modified during the testing process. After modification, the Lifepak 10 was identified as the -59 (PN 804200-59) hereinafter referred to as the -59. The Physio-Control Corporation requested that Armstrong Laboratory evaluate the Lifepak 10 Monitor/Defibrillator/Pacemaker, PN 804200-59 and its auxiliary power supply to determine its compatibility with aeromedical aircraft systems and the airborne environment.

DESCRIPTION

The LIFEPAK 10-59 is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring, and the new noninvasive pacing option (Fig. 1). A Military Auxiliary Power Supply (MAPS), model 806311-07, is designed to allow the -59 to be powered from a 120 VAC/60 Hz or 120 VAC/400 Hz source. Additionally, the -59 can receive power via any one of three rechargeable nickel-cadmium (Ni-Cad) batteries located on the top face of the monitor. The duration of an individual battery's life varies as a function of the -59's operating mode as well as the level and frequency of defibrillations. The specification for the battery life defines a range of 25-45 minutes.

The defibrillator offers eight energy levels at which it is able to deliver a monophasic DC defibrillating pulse. These energy levels range from 5 to 360 joules and may be delivered through standard paddles, clip-on posterior or pediatric paddles, or FAST-PATCH disposable defibrillation/electrocardiogram (ECG) electrodes.

The -59 model incorporates a noninvasive pacing option with a control panel located on the top of the monitor. This panel visibly distinguishes this model from the previously approved -43 model (Fig. 2). The pacer is a demand or synchronous pacer. Therefore, when the pacer is operational, the defibrillator is able to monitor a patient's ECG waveform and deliver an electrical stimulus when normal wave activity is not

detected. If the detected ECG waveform is normal, the pacer remains inhibited and no stimulation is delivered to the patient.

The front panel of the -59 contains the status display, monitor controls and cardioscope. The status display indicates heart rate, available energy, lead selected, SYNC mode, DIAG mode, pacing current and rate, pacing electrode connection message, and service indicator. The cardioscope is a non-fade display that sweeps at 25 mm/sec from right to left. The monitor controls are the following: ECG size - adjusts ECG gain; QRS volume - adjusts volume of QRS audible detector; Freeze - momentarily halts ECG trace on cathode ray tube display; CODE summary - activates a code summary printout; Record - activates strip chart recorder, activates Diagnostic mode if held for more than one second; CAL - sends 1 mV calibration pulse to monitor input; SYNC - triggers energy delivery to patient's QRS complex; and Lead Select - selects ECG input as paddles, I, II, or III. The energy select and charge controls are located on the paddles. Each paddle has a discharge control that must operate in conjunction with each other in order to discharge; depressing only one control will not cause the paddles to discharge. If the paddles are charged and not actively discharged within 60 seconds, the energy will automatically discharge internally.

The following information defines the general specifications of the -59 defibrillator. Size: 10.4 X 40.6 X 37 cm (4 X 16 X 14.6 in). Weight: 9 kgs (20 lbs). Heart Rate Range: 20 - 295 BPM. Pacing Rate Range: 40 - 170 BPM. Pacing Current Range: 0-200 mA. Available Energy Range: 0-360 joules in eight discrete energy levels. Lead Selection: paddles, I, II, III. Printer speed: 25 mm/sec. The LIFEPAK 10-59 comes with both Operating Instruction and Service Manuals.

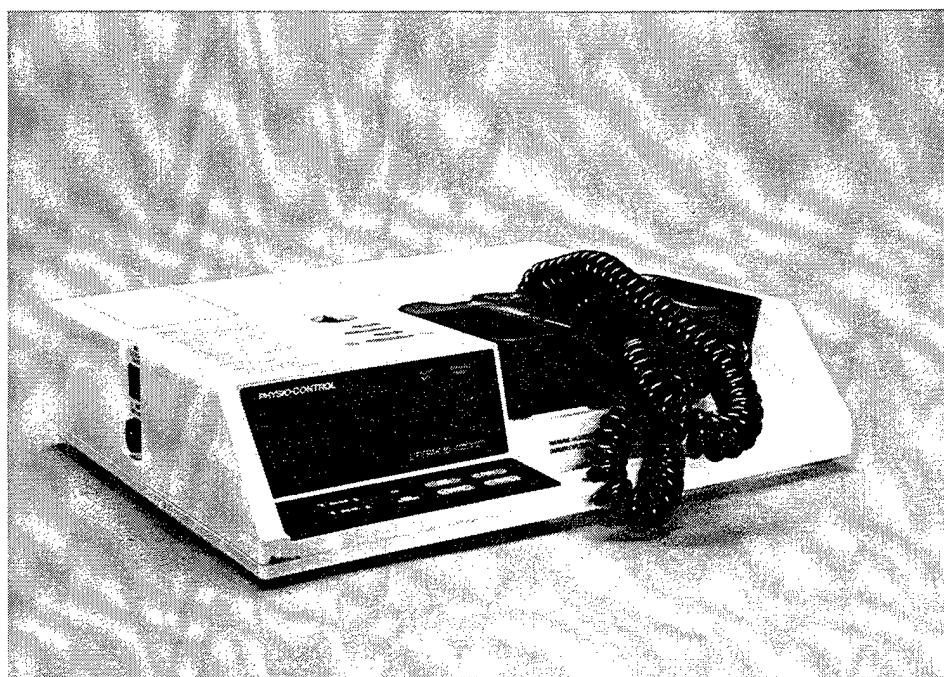


Fig 1. Lifepak 10-59 Defibrillator/Monitor/Pacemaker

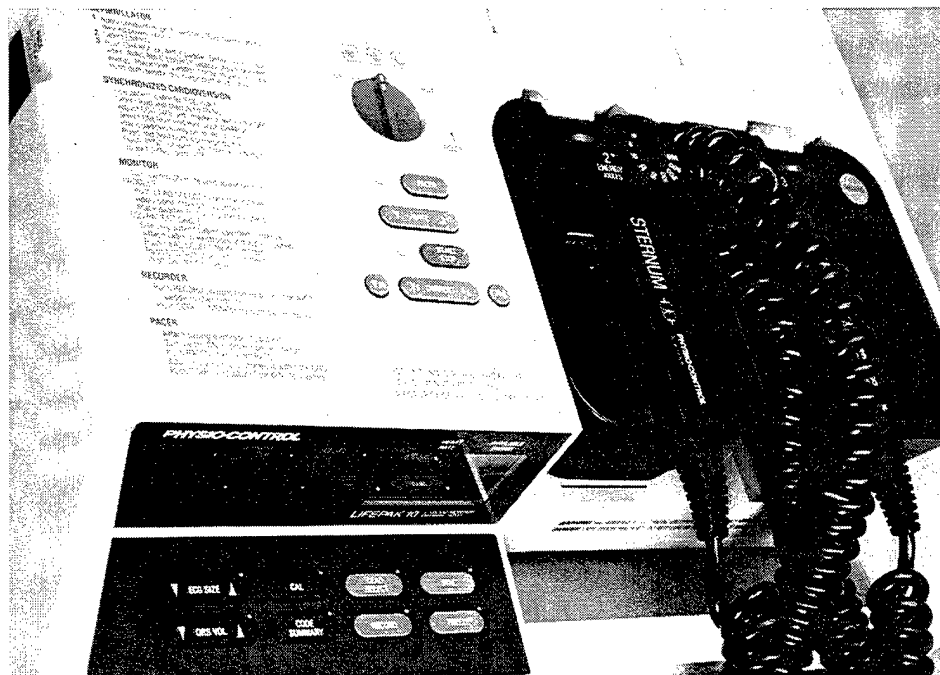


Fig 2. Pacer & power selection control panels on Lifepak 10-59

METHODS

Aeromedical Research personnel derived test methods, procedures and performance criteria from various military standards (1-4), nationally recognized performance guidelines (5-6), Aeromedical Research Procedure's Guide (9), and the LIFEPAK 10-59 Operating Instructions and Service Manuals (10). A test setup and performance check were developed to evaluate the -59's performance throughout testing.

BASELINE PERFORMANCE

The baseline performance assessment involved an initial inspection, electrical safety analysis, and following development of a specific test procedure for the device, a baseline performance check.

Initial Inspection

The -59 and MAPS were inspected for quality of workmanship, production techniques and potential damage incurred during shipment.

Electrical Safety

Biomedical Equipment Technicians and Aeromedical Research Engineers performed this evaluation on the -59 and MAPS to ensure the safety of both the equipment operator and the patient. This assessment involved measuring the equipment's leakage current and ground to chassis resistance while the unit operated from 115VAC/60Hz, and 115VAC/400Hz, in addition to a general inspection of the device. The required limits are established in National Fire Protection Agency (NFPA) 99 Health Care Facilities Code (6), Equipment Management in Hospitals AFI 41-201(7), and Electrical Shock Hazards AFI 41-203 (8).

Test Setup and Performance Check

A test setup and performance check were developed to evaluate the -59 and MAPS's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

a. Test Setup. One, of the following two analyzers, was connected to the ECG port on the monitor and provided the ECG waveform for the -59 during the monitor portion of testing: the Lionheart Multiparameter Simulator or the Impulse 4000 Analyzer. The three ECG leads were attached to the corresponding color-coded receptacles on the analyzer. The Lionheart settings were the following: Lead Select, I/II; ECG amplitude, 1.0; and ECG BPM, beats per minute, 60. The Impulse selections were the following: ECG mode, Normal Sinus Group (NORM), and 60 beats per minute. The Impulse 4000 also analyzed the defibrillator portion of the -59 when it is operating in the DEFIB mode. Additionally, the Impulse 4000 analyzed the pacer option of the -59, and its settings were the following: PACER mode, Internal 50 ohms load, PULSE and TEST. One of the three Ni-Cad batteries or the MAPS provided power to the -59. The -59 was configured as follows: Lead Select, II; ECG size that allowed for the largest view of the waveform; pacer settings on 100 mA and 100 BPM when pacer was activated; SYNC mode selected (where applicable); when in SYNC mode, ECG size control was adjusted such that the SYNC marker was positioned on the upper portion of the QRS complex.

b. Performance Check. As the -59 monitored the ECG waveform, defibrillator energy levels were selected and the paddles subsequently discharged into the energy determining device. The performance check included discharging the paddles a number of times at both a high-energy level, 360 joules, and a low-energy level, 10 joules. Additionally, the baseline performance check included testing synchronized defibrillation at an energy level of 50 joules. Aeromedical Research personnel utilized the ECG trace to visually confirm whether or not the defibrillator discharged at the appropriate location on the waveform. The performance check concluded with the verification of the pacer output and recorder function. The Impulse 4000 monitored the pacer, ensuring the accuracy of the pacing frequency and amplitude.

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern for equipment to be used on USAF aeromedical evacuation aircraft. This is mainly for the safety of everyone on board the aircraft and the effects of excessive electromagnetic emissions may have on aircraft navigation and communication equipment. Additionally, medical devices may be susceptible to fields generated by the aircraft equipment or other medical devices, and may malfunction in their presence.

The -59 and MAPS were evaluated for compliance with MIL-STD-461D by WL/AAWA-2, Wright-Patterson AFB, personnel in their electromagnetic compatibility facility, with Aeromedical Research and Physio-Control engineers present. ASC/ENAI personnel evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102): "Radiated Emissions, Electric Field, 10 kHz to 18 GHz." For Air Force aircraft applications, radiated emissions were tested in a range of frequencies from 2 MHz - 1 GHz. This test determined the amount of EMI emitted by the equipment during its operation. This test was performed to ensure that the device did not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment).

b. Conducted Emissions (CE-102): "Conducted Emissions, Power Leads, 10 kHz to 10 MHz." For Air Force aircraft applications, conducted emissions were tested throughout the band of 10 kHz - 10 MHz. This test measured emissions generated by the medical device along its power supply lines. This test was performed to ensure that operating the device using line power did not affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103): "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz." For Air Force aircraft applications, radiated susceptibility was tested in a frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). This test determined whether or not the device would withstand pre-defined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101): "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz." For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test determined whether the components "withstood ripple voltages associated with allowable distortion of power source voltage wave forms."(1)

e. Conducted Susceptibility (CS-114): "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz." For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band, from 10 kHz to 200 MHz. This test was performed to determine whether "simulated currents were developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."(1)

f. Conducted Susceptibility (CS-115): "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation." This test was performed to ensure the -59 could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse." (1)

During emissions testing, all options were operating for the duration of the test to create the "worst case" emissions scenario. During the first few frequency sweeps, the -59 defibrillator paddles were discharged at intervals. However, it was more than apparent that this caused it to exceed limits substantially and, therefore, testing continued with the -59 in the monitor/pacing mode. Throughout the testing, the Recorder (printer) ran continuously and the QRS beep sounded at maximum volume. For susceptibility testing, the -59 was operated individually in the pacing mode and in the monitoring mode. In the monitoring mode, the paddles were charged and discharged at intervals, for two reasons: First, it allowed researchers to crudely determine if EMI would cause the equipment to defibrillate at times other than when the operator depressed the discharge buttons; and second, energy defibrillation levels and monitor function could be confirmed. Aeromedical Research personnel were unable to test the SYNC function because it would have required exposure to high levels of electromagnetic radiation. For both emissions and susceptibility testing, the -59 was tested for operation on 115VAC/60Hz, 115VAC/400Hz, and internal batteries.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (810E). Vibration testing was conducted at Aeromedical Research's vibration facility. This testing involved a set of operational tests performed along each of the -59's three axes, X, Y, and Z, with the -59 and MAPS mounted on the NATO litter segment on the vibration table as they would be in the aircraft. They were subjected to vibration curves with slightly modified levels and lengths from those derived from MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17 (Fig 3).

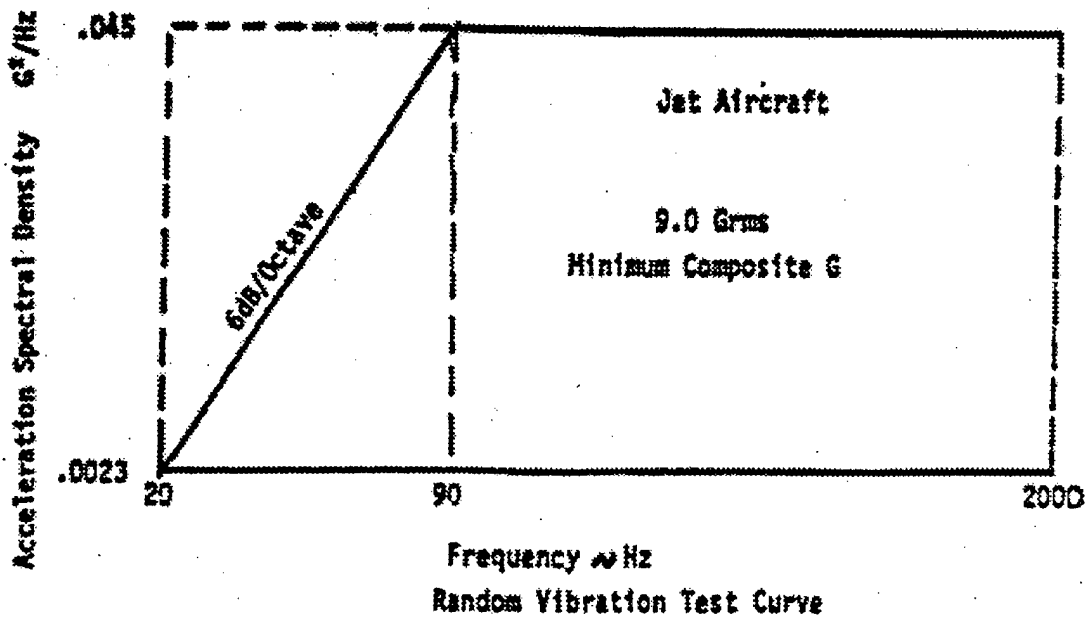
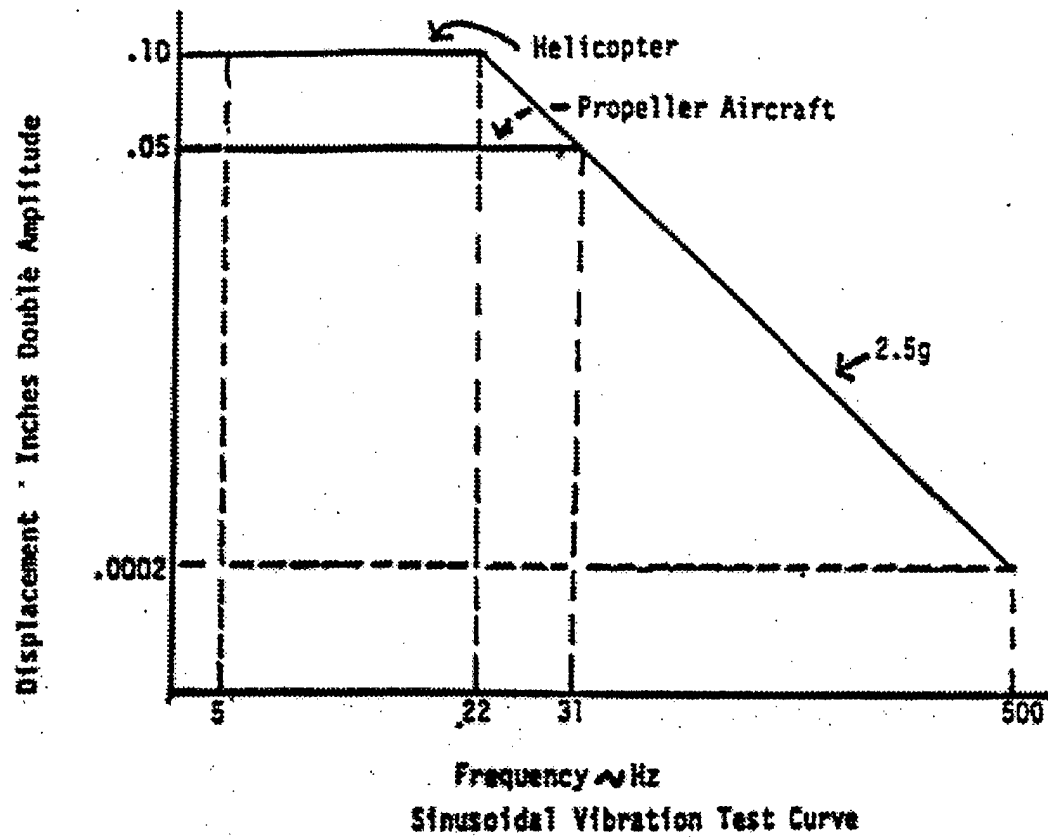


Fig 3. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ALTITUDE/RAPID DECOMPRESSION

Testing was conducted in the Armstrong Laboratory research chambers which were operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

a. Hypobaric Chamber Testing: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft that are characterized as opportune aircraft available for use in aeromedical evacuation pressurize their cabin to barometric pressures equivalent to 8,000-10,000 feet above sea level. However, the differences in pressures can be critical to the effective operation of some medical equipment. The -59 and MAPS altitude testing consisted of operating the -59 while ascending from ground level to 10,000 feet (maintaining altitude for one hour) and then descending back to ground, at rates of 5000 ft/min, while stopping at 2000 ft increments to allow for performance checks.

b. Rapid Decompression Testing: Rapid decompressions are caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression and ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The -59 and MAPS operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft (2,438 meters) altitude. Then, the chamber altitude was brought to 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft for a few minutes, and then brought back down to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The -59 was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground. The simulator equipment remained outside the chamber. Connectors joining the Impulse analyzer and the -59 and the power connector to the MAPS were run through putty-sealed access ports in the chamber walls.

THERMAL/HUMIDITY

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated under severe environmental conditions "without experiencing physical damage or deterioration in performance." Extreme environmental conditions can have numerous detrimental effects on medical equipment including, but not limited to, the following: changes in material characteristics and material dimensions, possible overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory,

Brooks AFB, TX. The -59 and MAPS were placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup were outside the chamber. For operational tests, the -59 was monitored continuously, and a performance check was conducted every fifteen minutes. For storage tests, the -59 and the MAPS were placed in the chamber and remained nonoperational throughout the storage portion of the test. The following describe the conditions of the environmental tests performed:

- a. Humidity: 94+/-4% Rh, 85°F+/-3.6°F (29.5°C+/-2°C) for 4 hrs
- b. Hot Temp Operation: 120°F+/-3.6°F (49°C+/-2°C) for 2 hrs
- c. Cold Temp Operation: 32°F+/-7.2 (0°C+/-4°C) for 2 hrs
- d. Hot Temp Storage: 140°F+/-3.6°F (60°C+/-2°C) for 6 hrs
- e. Cold Temp Storage: -40°F+/-3.6°F (-40°C+/-2°C) for 6 hrs

AIRBORNE FEASIBILITY

Airborne feasibility evaluations are an invaluable means of validating a piece of equipment for clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent casualty care issues are adequately addressed by the test protocols. Ensuring safe and effective clinical operation of medical equipment is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by aircraft-qualified Aeromedical Research technicians on board both a C-9 and C-141 aeromedical evacuation mission. The -59 and MAPS were secured to a litter and evaluated throughout the flights by Aeromedical Research technicians as well as the other members of the aeromedical evacuation crew. Human factors characteristics, securing methods, and equipment setup times and locations were also evaluated.

RESULTS

BASELINE PERFORMANCE

Initial inspection results revealed no manufacturing defects. The -59 leakage current and ground resistance characteristics remained within allowable limits for battery and 115VAC/60Hz operation, with one exception. When a battery well was empty, the exposed terminal leads exhibited leakage currents in excess of NFPA 99 limits. By ensuring the batteries are in place, potential electrical shock can be avoided. When the -59 was tested on 115VAC/400Hz, the leakage current

characteristics remained above allowable limits. The -59 leakage current characteristics were not within allowable limits for 115VAC/400Hz operation; therefore, the 115VAC/400Hz operation of the -59 is not authorized for aeromedical evacuation flights.

ELECTROMAGNETIC COMPATIBILITY

The -59 and MAPS passed all phases of electromagnetic compatibility testing in both the monitoring and pacing mode. However, because of potential differences in electromagnetic compatibility characteristics when pacing a human verses a simulator, Aeromedical Research was unable to determine the airworthiness of the pacing mode. An in-depth research project is needed to study the effects of pacing on human subjects to characterize the effects of the human's interaction with the system. ASC/ENAI, Wright-Patterson AFB, has currently certified the -59 and MAPS for use in aeromedical evacuation on all Air Force aircraft while operating on 115VAC/60Hz or battery power.

VIBRATION

The -59 and MAPS operated within manufacturer's specifications throughout the vibration testing.

ALTITUDE/RAPID DECOMPRESSION

a. Altitude: The -59 and MAPS operated within manufacturer's specifications during altitude testing.

b. Rapid Decompression: The MAPS operated within manufacturer's specifications following each rapid decompression and did not present a safety hazard throughout the decompression. The -59 failed the 60-second decompression. The pacer panel became inoperative as the chamber was brought down from 40,000 ft. The pacer circuit board contains a gasket that vented on ascent, but was unable to let air "back in" upon descent, essentially producing a vacuum on the pacer control buttons, depressing them all at once, thus inactivating the pacer panel. Physio-Control engineers made modifications to the newer -59 model pacer board, and the -59 successfully completed the series of decompressions.

THERMAL/HUMIDITY

The -59 and MAPS operated within manufacturer's specifications during all five phases of testing.

AIRBORNE FEASIBILITY

The inflight evaluation of the -59 and MAPS was performed on a C-9 aeromedical evacuation mission and C-141 aeromedical readiness mission and confirmed that the units would operate successfully during all phases of flight. The Vanner Inverter successfully supplied power to the MAPS during the C-141 mission. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems.

CONCLUSIONS

Aeromedical Research found the defibrillator/monitor portions of the LIFEPAK 10-59 acceptable for use on all Air Force aeromedical evacuation aircraft while operating on 115VAC/60Hz or battery power with the recommendations and restrictions listed below. The -59 operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The pacer portion of the -59 is "NOT" approved for use in the aeromedical evacuation aircraft; however, the inactive pacer portion survived the flight environment and is an available option for "off the aircraft" use. The following recommendations and operational restrictions accompany the airworthiness approval of the -59 and MAPS:

a. Add the following warning to the Operating Instructions and Service Manual:

WARNING: Restrictions for use on USAF aircraft: The pacing option is not to be operational at any time during flight. The AC Auxiliary Power Supply can only be used on 115VAC/60Hz. Ensure that there is a battery in each well while operating on 115VAC/60Hz.

b. Attach a warning label near the pacer control panel that reads, "Do not operate pacer in flight."

c. Attach a warning label on the AC Auxiliary Power Supply that reads, "Do not operate on 115VAC/400 Hz."

d. Attach a warning label near the battery wells that reads, "Place battery in each well before operating from 115VAC/60Hz."

e. Inform Aircraft Commander that a cardiac monitor will be in use on board, and that they will be notified if defibrillation is to occur because of the possibility of electromagnetic interference with aircraft navigation and communication equipment.

REFERENCES

1. MIL-STD-461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e
2. MIL-STD-462 D, Measurement of EMI Characteristics.
3. MIL-STD-810 E, Environmental Test Methods and Engineering Guidelines
4. MIL-STD-1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. Emergency Care Research Institute (ECRI), Defibrillator/Monitor/Pacemakers, Vol 22 Nos. 5-6.
6. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
7. AFI 41-201, Equipment Management in Hospitals
8. AFI 41-203, Electrical Shock Hazards
9. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory
10. Lifepak 10 Service Manual and Operating Instructions

APPENDIX A

APPENDIX A **SPECIFICATIONS OF THE LIFEPAK 10-59** **DEFIBRILLATOR/MONITOR/PACEMAKER**

ECG MONITOR

ECG LEAD SELECTION
INPUT

Paddles, I, II, III
Isolated ECG via QUIK-LOOK defibrillation
paddles, FAST-PATCH electrodes, or 3 lead
ECG cable

ELECTRICAL ISOLATION AND SHIELDING

Input protected against high voltage
defibrillator pulses and radio frequency
interference per FDA Standards MDS-210-
0004. RF interference depends on distance
from RF source, radio output power,
radiating efficiency, vehicle environment,
etc.

ECG CABLE LENGTH

3.96 m (13 ft) total length; 3.05m (10 ft)
with .91m leads (3 ft)

COMMON MODE REJECTION

Minimum 100dB with respect to chassis
ground at 60Hz, 65dB minimum with
respect to isolated ground

CARDIOSCOPE DISPLAY

Size:

72.5 mm(2.85in) x 43.5 mm(1.7in), non-
fade

Sweep Speed:

25 mm/sec

Frequency Response:

monitor freq. resp. (domestic)

1 to 30Hz, -3dB

monitor freq. resp. (agency)

5 to 25Hz, -1.4dB

expanded freq. resp. while recorder
in DIAG mode

.05 to 30Hz, -3dB

paddles freq. resp.

2 to 20Hz, -2dB

STRIP CHART RECORDER

Paper size:

50 mm x 30 m (100 ft)

Paper speed:

25 mm/sec

Frequency response:

monitor freq. resp. (domestic)

1 to 30Hz, -3dB

monitor freq. resp. (agency)

.5 (-1.4dB) to 40 (-3dB)Hz

diagnostic freq. resp.

.05 to 100Hz, -3dB

paddles freq. resp.

2 to 20Hz, -2dB

CODE SUMMARY

domestic

1 to 30Hz

agency

.5 to 40Hz

Annotation:

Includes time, date, lead, gain, heart rate,
defibrillation and/or pacing parameters

CODE SUMMARY critical event record

Digitally stored record of critical ECG and
device parameters

STATUS DISPLAY

HEART RATE (bpm):

3 digit readout displays rates from 20-295
bpm

AVAILABLE ENERGY:

0-360 joules

Pacing rate (optional):

40-170 bpm

Pacing current (optional):

0-200 mA

DIAG:

Indicates recorder frequency response is
.05 to 100Hz, -3dB

MONITOR CONTROLS

ECG SIZE:	adjusts ECG gain
QRS VOL:	adjusts loudness of QRS beeper
FREEZE:	momentarily halts the ECG trace on CRT
CODE SUMMARY:	activates code summary printout
RECORD:	activates strip chart recorder; activates diagnostic mode if held for more than 1 second (when enabled)
CAL:	sends calibration pulse to monitor input
SYNC:	triggers energy delivery to patient's QRS complex
LEAD SELECT:	selects ECG input: Paddles, I, II, III
ECG OUTPUT	
Unmodulated:	1 V/mv at x1 gain
Modulated:	1400Hz+/-2% center frequency, 1Vrms+/-10%
Frequency response:	matches strip chart recorder

DEFIBRILLATOR

WAVEFORM	5msec monophasic pulse (Edmark) per AAMI spec
ENERGY SELECT	0,5,10,20,50,100,200,300,360 joules
CHARGE TIME	360 joules in less than 12 seconds above 0°C
PADDLE AREA	82 cm ² (adult) 16 cm ² (pediatric)
CORD LENGTH	2.3 m (7.5 ft)
SYNCHRONIZER	Energy discharge within 20msec of sync maker on cardioscope (triggers to patient generated QRS complex)
PADDLE CONTROLS	CHARGE (with indicator light) RECORD (activates strip chart recorder) ENERGY select dial (rotating dial; 0 to 360 joules) (dual energy discharge buttons, one on each paddle)

QUIK-PACE NONINVASIVE PACEMAKER

OUTPUT RATE	40-170bpm
RATE ACCURACY	+/-1.5% over entire range
OUTPUT WAVEFORM	Monophasic, truncated, exponential current pulse, 20+/-1msec duration measured at output current, >=10 mA peak
OUTPUT CURRENT	0-200 mA+/-5% or 5 mA (whichever is greater) at 700 ohms. Output variation less than 5% over the load range of 100 -1500 ohms
REFRACTORY PERIOD	
Pacing rates	Refractory period
40-90	340msec+/-3%
100	300msec+/-3%
110-120	250msec+/-3%
130-140	220msec+/-3%
150-170	200msec+/-3%

ENVIRONMENTAL

TEMPERATURE

Standby:

5 to 55°C (41 to 131°F)

Operating:

-10 to 55°C (14 to 131°F) after minimum
2 hour storage at standby temperature
-30 to 65°C (-22 to 149°F)

Storage (exclusive of batteries):

HUMIDITY

0 to 95% (non-condensing) 0 to 34°C
(32 to 93.2°F)

0 to 80% (non-condensing) 35 to 55°C
(95 to 131°F)

ATMOSPHERIC PRESSURE

797 to 439 mmHg (-570 +15,000 ft)

VIBRATION

Helicopter aircraft:

MIL-STD-810D, method 514.3 (category
6). Test levels per US Army Aeromedical
Research Laboratory Report no. 91-14,
section 2.6.3 (March 1991), (UH-1
helicopter, floor under co-pilot's seat).
Test level of .0016g²/Hz, the maximum
level per figure 32(31) of ECRI Report,
contract no. 223-77-5035. Prepared for
FDA (April 1979).

Fixed-Wing, Turboprop Transport:

CAUTION: To help prevent component damage, the device should not be mounted near
vibration sources such as engine struts and landing gear.

SHOCK(DROP)

With carrying case (soft case), passes drop
of 43 inches from the handle (30 inches
from case). This exceeds test levels per
ECRI report, contract no. 223-77-5035,
prepared for FDA (April 1979).

SEALED CASE

MIL-STD-810E and IEC 601-2-4

GENERAL

BATTERY

3 NiCad batteries, 12V, 1 amp hours each.
A new battery registering at least 100%
capacity on the Battery Support System will
provide at minimum:

*45 minutes of monitoring, or

*30 minutes of pacing, or

*25 discharges at 360 joules/battery

HEIGHT

10.4 cm (4 in)

WIDTH

40.6 cm (16 in)

DEPTH

37 cm (14.6 in)

WEIGHT

9 kg (20lbs)

All specifications are at 25°C unless otherwise stated.